

CLAIMS

1. A process for analysing the saccharide content of a composition, wherein:

(a) the composition comprises a capsular saccharide from serogroup C of *Neisseria meningitidis* and one or both of: (i) a capsular saccharide from serogroup W135 of *Neisseria meningitidis*; and/or (ii) a capsular saccharide from serogroup Y of *Neisseria meningitidis*;

(b) the process comprises a step of analysing the sialic acid content of the composition, and: (i) if the composition includes a serogroup W135 saccharide, a step of analysing the galactose content of the composition; (ii) if the composition includes a serogroup Y saccharide, a step of analysing the glucose content of the composition;

(c) if the composition includes a serogroup W135 saccharide, the content of serogroup W135 saccharide in the composition is determined according to the results of the galactose analysis from step (b);

(d) if the composition includes a serogroup Y saccharide, the content of serogroup Y saccharide in the composition is determined according to the results of the glucose analysis from step (b); and

(e) the content of serogroup C saccharide in the composition is determined by comparing the results of the sialic acid analysis with: (i) if the composition includes a serogroup W135 saccharide but not a serogroup Y saccharide, the results of the galactose analysis from step (b); (ii) if the composition includes a serogroup Y saccharide but not a serogroup W135 saccharide, the results of the glucose analysis from step (b); or (iii) if the composition includes both a serogroup W135 saccharide and a serogroup Y saccharide, the combined results of the glucose and galactose analyses from step (b).

2. The process of claim 1, wherein the composition comprises capsular saccharide from all three of serogroups C, W135 and Y of *Neisseria meningitidis*.

3. The process of claim 2, wherein the composition comprises one or more further capsular saccharide(s).

4. The process of claim 3, wherein the one or more further capsular saccharide(s) is/are selected from the group consisting of: a capsular saccharide from serogroup A. of *N.meningitidis*; and a capsular saccharide from *Haemophilus influenzae* b.

5. The process of any preceding claim, including a step of treating the composition in order to depolymerise the capsular saccharides to give their constituent monosaccharides.

6. The process of any preceding claim, wherein sialic acid content, glucose content and/or galactose content are measured by high performance anion exchange chromatography, optionally with pulsed amperometric detection.

7. The process of any preceding claim, wherein the process also includes step(s) in which one of more of the following components or properties is/are analysed: osmolality, pH, degree of polymerisation for individual saccharides or conjugates, protein content, aluminium content, detergent content, and preservative content.
- 5 8. The process of any preceding claim, wherein the capsular saccharides are derived from a saccharide-protein conjugate.
9. The process of claim 8, wherein the protein in the conjugate is a bacterial toxin or toxoid.
10. The process of claim 9, wherein the toxin or toxoid is selected from the group consisting of: diphtheria toxoid; tetanus toxoid; the CRM197 diphtheria toxin derivative; and protein D from
10 *H. influenzae*.
11. A process for analysing a composition, wherein:
- 15 (a) the composition comprises a conjugate of a capsular saccharide from serogroup C of *Neisseria meningitidis* and one or both of: (i) a conjugate of a capsular saccharide from serogroup W135 of *Neisseria meningitidis*; and/or (ii) a conjugate of a capsular saccharide from serogroup Y of *Neisseria meningitidis*;
- (b) the composition may comprise the capsular saccharides in unconjugated form;
- (c) the content of any unconjugated capsular saccharides is determined by the process of any one of claims 1 to 7;
- 20 (d) the content of conjugated capsular saccharides is determined by the process of any one of claims 1 to 7; and, optionally,
- (e) the ratio of conjugated:unconjugated saccharide in the composition is calculated for one or more of the capsular saccharides.
12. A process for quantifying saccharides from individual serogroups within a mixture of capsular saccharides from at least two different meningococcal serogroups, wherein: (a) the different
25 serogroups comprise serogroup C and one or both of: (i) serogroup W135 and/or (ii) serogroup Y; (b) the process comprises a step of depolymerising the capsular saccharides within the mixture, to give a depolymerised mixture; and (c) the different serogroups are quantified by comparing the monosaccharide composition of the depolymerised mixture.
13. A method for releasing a vaccine for use by physicians, comprising the steps of:
- 30 (a) manufacturing a vaccine containing a conjugate of a capsular saccharide from serogroup C of *Neisseria meningitidis* and one or both of: (i) a conjugate of a capsular saccharide from serogroup W135 of *Neisseria meningitidis*; and/or (ii) a conjugate of a capsular saccharide from serogroup Y of *Neisseria meningitidis*; (b) analysing the amount of conjugated and/or unconjugated saccharide in the vaccine for each of said capsular saccharides; and, if the results

from step (b) indicate a saccharide content acceptable for clinical use, (c) releasing the vaccine for use by physicians.

14. Two batches of a vaccine, wherein:

5 (a) each of the batches of vaccine comprises: a conjugate of a capsular saccharide from serogroup C of *Neisseria meningitidis* and one or both of: (i) a conjugate of a capsular saccharide from serogroup W135 of *Neisseria meningitidis*; and/or (ii) a conjugate of a capsular saccharide from serogroup Y of *Neisseria meningitidis*;

(b) the concentration of conjugated serogroup C saccharide in the first batch is C_1 ;

(c) the concentration of conjugated serogroup C saccharide in the second batch is C_2 ;

10 if applicable, (d) the concentration of conjugated serogroup W135 saccharide in the first batch is W_1 ;

if applicable, (e) the concentration of conjugated serogroup W135 saccharide in the second batch is W_2 ;

15 if applicable, (f) the concentration of conjugated serogroup Y saccharide in the first batch is Y_1 ;

if applicable, (g) the concentration of conjugated serogroup Y saccharide in the second batch is Y_2 ;

and wherein (h) the ratios C_1/C_2 , W_1/W_2 and Y_1/Y_2 are each between 0.90 and 1.10.

15. The batches of claim 14, wherein: (i) the concentration of unconjugated serogroup C saccharide
20 in the first batch is C_3 ; (j) the concentration of unconjugated serogroup C saccharide in the second batch is C_4 ; if applicable, (k) the concentration of unconjugated serogroup W135 saccharide in the first batch is W_3 ; if applicable, (l) the concentration of unconjugated serogroup W135 saccharide in the second batch is W_4 ; if applicable, (m) the concentration of unconjugated serogroup Y saccharide in the first batch is Y_3 ; if applicable, (n) the concentration of
25 unconjugated serogroup Y saccharide in the second batch is Y_4 ; (o) the ratios C_3/C_4 , W_3/W_4 and Y_3/Y_4 are each between 0.90 and 1.10, and preferably are each between 0.95 and 1.05.

16. The batches of claim 15m wherein (p) the ratios C_3/C_1 , C_4/C_2 , W_3/W_1 , W_4/W_2 , Y_3/Y_1 and Y_4/Y_2 are each less than 0.20.

17. A computer apparatus adapted to perform the process of any one of claims 1 to 12.

30 18. A computer program for analysing the saccharide content of a composition as defined in claim 1, comprising a program module for: (a) receiving data on the sialic acid content, and on the glucose and/or galactose content, of a sample; and (b) calculating from those data the content of capsular saccharide from serogroup C and from serogroup W135 and/or Y.